Patent regulation in North-South and South-South Trade Agreements

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Abstract

The article provides a comparative examination of patent provisions in both North-South and South-South Preferential Trade Agreements (PTAs). It assesses whether the flexibilities of World Trade Organization Agreement on trade-related aspect Intellectual Property Rights (TRIPS), are getting eliminated, preserved or affirmed in the studied PTAs. The article studies the PTAs of both the United States and European Union with developing countries as examples of North-South agreements, and the PTAs of both China and India with developing countries as examples of South-South agreements. The PTAs of US show systematic efforts to eliminate TRIPS flexibilities. EU chapters on IP engage partner countries to accede or comply with WIPO treaties in its earlier versions, and converge toward US approach in its latest versions. By contrast, China PTAs affirm commitment under TRIPS and emphasis some of its flexibilities. Patent related issues are absent from India's PTAs.

Keywords: Patent, TRIPS flexibilities, Preferential Trade Agreements, TRIPS plus.

1- Introduction

Industrial development is a long-term process of accumulation of diversified technological capabilities (Stiglitz et al, 2009). Access to knowledge and the accumulation of diversified technological capabilities are essential aspects of industrialization process (Cimoli et al, 2014). In fact, what separates developed from developing countries today is as much a gap in knowledge as a gap in resources. An essential aspect of "catching up" by developing countries is the emulation of technological leaders (Reinert, 2009) and the rapid accumulation of the knowledge and capabilities needed in order to sustain processes of technical learning.

However this accumulation is influenced by broad array of policies and the existence of supporting institutions, including those governing the modes though which individuals and organizations can claim the legal rights to the exclusive exploitation of their knowledge. To put another way, technological capacities accumulation is influenced by the governance of intellectual property rights (IPRs) (Cimoli et al, 2014).[1]

1 Cimoli, Dosi and Stiglitz, (2009) noted that these policies historically happened to involve, to different degrees and according to specific local conditions, the following elements consistent with the ingredients we have previously identified in industrialization processes: (i) state ownership; (ii) selective credit allocation; (iii) favorable tax treatment to selective industries; (iv) restrictions on foreign investment; (v) local context requirements; (vi) special IPR regimes; (vii) government procurement; and (viii) promotion of large domestic firms.

Tight IPR regimes hinder the activities of reverse engineering and imitative experimentation which are typically at the core of the development process, Consequently they hinder the development of local technological capabilities in general and absorptive capabilities in particular (Dosi and Stiglitz, 2014).

One of the well documented historical fact, it is the laxity or the absence of IPR in nearly all instances of successful industrialization experience to the extent that the emulation of the technological leaders can be identified as one of the few constants across those experience (Reinert, 2009, Cimoli et al, 2014).

A major change was the incorporation of (IPR) in the international trade domain, culminating in the adoption of WTO agreement on Trade related Intellectual Property Rights (TRIPs). TRIPS agreement represents a historical impediment, in relative and absolute terms, to policies aiming at the structural transformation of developing economies.

However, even if IPR homogenization reduces the spaces for policy maneuver, it did not end the "implementation game" at the national level (Deere, 2009). Within the new international framework, there remains room for countries to push for some strategic intellectual property management. TRIPs agreement provides some flexibilities, although scant, that may be further exploited and adapted consistently with industrial policy framework. However, legal feasibility and awareness of the existence of these flexibilities are not sufficient for countries to take advantage of them for two reasons.

Moreover, those flexibilities are getting eliminated by some trade agreements that incorporate IPR standards which are even higher than those agreed under TRIPS agreement (TRIPs *Plus*).

The paper provides *de jure* comparative examination of patent provisions under North-South and South-South Preferential Trade Agreements (PTAs). More precisely, it investigates the state of the so-called "TRIPS flexibilities" under the PTA, whether eliminated, kept or affirmed.

As example of North-South PTAs the study covers 9 agreements of United State and 10 European Union, signed with developing countries. As example of South-South PTAs agreement, the study covers 5 Chinese agreements and 8 Indian with developing countries. The aim behind the choice of these countries is to evaluate if there are significant differences between the conduct of emerging economies and core countries in their economic agreements with developing countries.

The articles would examine the level to which the US and the EU'S PTAs limit the possibility to design patent regulation at the national level, in a manner that favors the upgrading of national technological capabilities, though the elimination of "TRIPS flexibilities". In addition it aims to investigate any convergence in US and EU's approaches to patent over time.

In addition, it examines the extent to which the Chinese and Indian's PTAs preserve or affirm "TRIPS flexibilities". Moreover, it assesses if there is any convergence in south approaches to patent, through the example of Chinese and India. In addition empirical results would permit to estimate whether emerging economies, through the example of China and India, are promoting new institutions in international patent regulations through their PTAs.

Results shows, in accordance to previous studies, that US's PTAs eliminate systematically TRIPS Flexibilities. EU's PTAs have been changing through time. While it tended to eliminate some flexibility in earlier PTAs through the engagement to adhere to WIPO's treaties, the latest agreements join the US approach, eliminating more flexibility.

China's PTAs range from the absence of the mere term "intellectual property" and "patent" in some PTAs, to the inclusion of chapter on IPR in others. Whenever such chapters are included, all TRIPS flexibilities are maintained. Moreover, flexibilities were confirmed through their recurrent reference to Doha declaration. India's PTAs introduce no regulations related to patent, and more generally to IPRs.

The article is structured as follows. Next section presents, briefly, the TRIPS flexibility and TRIPS plus concepts, which would be used to formulate an analytical framework that permits to analyze, comparatively, patent provisions in studied PTAs. Sections 4, 5, 6 attempt to deduce Patent approaches of US, EU and China respectively. Section 7 concludes.

2- TRIPs *Plus* commitments in PTAs

TRIPS has placed significant constraints on countries' autonomy in intellectual property matters. However, as a consensual outcome it has left room for variation across countries, labeled under the term "flexibilities". This term designates the various legal doctrines and mechanisms that help to mitigate the effects deriving from the exclusive rights conferred to patentee. The flexibilities are derived from (1) an explicit exception to private right of patent owner, (3) ambiguities in the text that allow for different modalities of implementation, (4) some provisions indicate the objectives to be met rather than the specific ways in which they may be achieved. The TRIPS flexibilities may be useful for different objectives, ranging from local production to the importation of protected products at the lowest possible price (Correa, 2014). The degree to which such flexibilities are incorporated

into national laws determine the room available to adopt measures to upgrade technological capacities of the local economy.

However, while developing countries have the right to exercise the flexibilities under the TRIPS Agreement, in reality it remains difficult for many of them to make effective use of them because of, *inter alia*, lack of infrastructural and technical expertise and lack of manufacture capacities. If IPR are enforced where productive and technological capabilities are weak and industrial policies are absent, countries have no bargaining power, and little capacity to recur to TRIPS flexibilities. At the same time, if these policy spaces remain unexplored and no active industrial policies are effectively implemented, the adoption of stronger IPR regimes will make the process of creation of capabilities even more difficult.

It could be useful to emphasis that the very term "flexibilities" is relative. Some flexibilities are considered as such only when compared, on the one hand, to the orthodox interpretations of TRIPS provisions; and on the other hand, when compared to TRIPS plus provisions included in some bilateral trade agreements.

TRIPS-plus is a concept which refers to the adoption of multilateral, plurilateral, regional and/or national intellectual property rules and practices which have the effect of reducing the ability of developing countries to protect the public interest. It covers both those activities aimed at increasing the level of protection for right holders beyond that which is given in the TRIPS Agreement and those measures aimed at reducing the scope or effectiveness of limitations on rights and exceptions (Dutfiel and Musungu, *2003)*. TRIPS plus includes any new standards that would limit the ability of these countries to:

• promote technological innovation and to facilitate the transfer and dissemination of technology;

• take necessary measures to protect public health, nutrition and to promote the public interest in sectors of vital importance to their socio-economic and technological development; or,

• take appropriate measures to prevent the abuse of intellectual property rights by right holders or the resort by right holders to practices which affect the international transfer of technology.

Based on both the abundant literature on TRIPS flexibilities (e.g. Mercurio, 2006; Shadlen, 2005; Matthias Lamping et al, 2014) and the author observations in studied PTAs, Table (1) present an analytical aiming at identifying TRIPS *plus* commitments in the studied PTAs. The framework would permit the comparison of studied PTAs to each other and to TRIPS commitments. It provides an overall view of TRIPS *plus* commitments as observed in the Studied 33 PTAs (Listed in table 2 in annex). In addition, it reports reference to Doha

Declaration and the Convention Biological Diversity, which could be considered TRIPS *minus*. India PTAs have no reference to IPR issues or patent, therefore it is not included in the table.

Table(1)

Analytical Framework	US									EU						China					
	Marroc	Bahrin	Oman	Jordan	CAFTA-Dr	Peru	Chile	Colombia	Panama	MED	Mexico	SouthAfrica	Chile	CARIFORUM	Peru and Colombia	ASEAN	Pakistan	Chile	CostaRica	Peru	SouthKorea
1-Reference to International Agreements																					
Doha Declaration on														x	x	x		x	x	x	x
Patent Law Treaty	x	x	x		x	x	x	x	x	x				x	x						
Patent Cooperation Treaty	x	x	x	x	x	x	x	x	x	x			x	x	x						x
UPOV 1991	x	x	x	x	x	x	x	x	x	x		x	x	x	x						
Budhapest	x	x	x		x	x		x	x	x		x	x	x	x						x
Convention on Biological diversity														x	x						
2-Patent Granting Conditions																					
Scope of patentability																					
Novelty	x	x	x		x	x	x	x	x												

	definition																				
	Industrial applicability definition	x		x		x	x		x	x											
	New uses for known products	x	x	x						x											
	Plant	x	x	x	x	x	x	x	x	x											
	Animal	x																			
Information disclosure		x		x			x		x	x											
Test and clinical data		x	x	x		x			x	x											
Right exhaustion and parallel importing		x	x	x		x	x	x	x	x											
Patent Duration		x	x	x		x	x	x	x	x											
Patent Revocation		x	x	x		x	x	x	x	x	x			x	x						
3- Exception to patent right																					
Compulsory Liecence																					
	Direct restriction				x																
	Indirect restriction	x	x	x		x	x	x	x	x											

3- US's Patent Approach in PTAs

US's PTAs seems to be consistent over time with little variation from agreement to another. It increases patent protection level in each aspect of TRIPS flexibilities, with respect to all product and with respect to specific product, i.e. Agrochemical and pharmaceutics. In addition US engage other parties to adhere, commit and comply with World intellectual Property Organization (WIPO) treaties. Paper discusses TRIPS *plus* commitment included in WIPO treaties on section on EU approach.

3.1- Patenting scope

US PTAs broaden the patentability scope by removing the ambiguity that exists under TRIPS and exporting the more liberal interpretation:

A - It defines "novelty" in a more expansive way, where goods can pass the novelty test and be granted a patent if the knowledge has been disclosed within the year prior to application.[2] During this period the inventor may search for financing or test the market for his/her invention before initiating the costly and complicated steps to patent the invention. In most countries, any disclosure annuls the novelty characteristic of an invention.

B - They mandate that patents be available for new uses of known products. The effect of this provision is to allow a first registrant of a new chemical product (especially pharmaceutical) to obtain protection even in the case of old and well known products, extending the patent term.

C - US own definition of Industrial applicability, that emphasis the "usefulness", was adopted3. An invention only needs to be operable and capable of satisfying some function of benefit to humanity. Thus, certain developments that do not lead to an industrial product may be patented. The U.S. rule permits the patentability of purely experimental inventions that cannot be made or used in an industry, or that do not produce a so-called technical effect, as illustrated by granting patent, for example, to methods of doing business (UNCTAD-ICTSD, 2005).

D - They Permit the patentability of excluded subject matter under TRIPS, that's plants and/or animals. The strongest agreement in this regard is US-Morocco, which explicitly mandates the provision of patent protection for life forms. Where plant patenting is not required, it introduce obligation to "undertake all reasonable efforts to make such patent protection available". In the absence of plant patents, at the very least, a UPOV 1991 system should be granted (this point will be discussed in the section on EU approach).

3.2- Disclosure requirements and data exclusivity

2 CAFTA-DR Art15.9.7, Chile Art 17.9.7, Colombia Art 16.9.7, Panama Art 15.9.7, Peru 16.9.7, Morocco Art 15.9.8, Oman 15.8.7; Bahrain Art 14.8.8,

[3] US PTA with Panama Art 15.9.11, Peru Art 16.9.11, Oman 15.8.11, Morocco Art 16.9.11, Colombia Art 16.9.11 and CAFTA-DR Art 15.9.11.

Disclosure provisions wording is more consistent with US law than the original provision of the TRIPS Agreement[4] (Morin, 2004), introducing a ceiling to the disclosure requirement. For instance, the expressions "to be made and used" and "without undue experimentation" are directly imported from US law. Indeed, this provision appears to forbid countries from asking for more than "information that allows the invention to be made and used" in order to accept a disclosure as sufficiently clear and complete. Experimentation is permitted under TRIPS. Here again US PTAs, limits this flexibility when specifying that "undue experimentation" are not permitted. However it doesn't define criteria about what do constitute "undue" experimentation.

Those provisions limit the ability to require the disclosure of the origin of genetic resources used in the development of biotechnological inventions, which is a demand of many developing countries rich with genetics resources. Finally, disclosure provisions in US PTAs eliminate the facultative requirements under TRIPS to demand the best mode of carrying out the invention.

US PTAs[5], prevent the later applicant and the national authority from disclosing or relying on the clinical studies and data provided by the original applicant when seeking to register the generic version of the drug or agriculture chemical product for a given period of time following the first registration (5 years for Pharmaceutical and 10 years chemical agriculture product). US PTAs include provision[6] which apply the same period of data exclusivity from the approval date in another country even if the manufacturer has not sought to register the drug in that particular country. Thus, a generic manufacturer wishing to market and distribute a generic whilst the period of data exclusivity is in force must conduct its own clinical trials and other data and submit its findings to the national authority. The end result of data exclusivity in third country being that the country does not have access to that particular drug or agriculture chemical product until the expiration of the data exclusivity period.

In addition, certains PTAs eliminate the Article 39.3 requirement in TRIPS which protects data only in cases where the pharmaceutical in question utilizes 'new chemical

[4] US PTAs with CAFTA-DR Art 15.9.9 Panama Art 15.9.9, Peru Art 15.9.9, Oman Art 15.8.10, Morocco Art 15.9.10, Colombia Art 16.9.9 and Bahrain 14.8.10.

[5] Bahrain Art 14.9.1, Oman Art 15.9.1, CAFTA-DR Art 15.10.1, Colombia Art 16.10.1, Morocco Art 15.10.1, Peru16.10.1 Panama Art 15.10.1 and Chile Art 17.10.1

[6] These provisions are found in FTAs between the US and CAFTA-DR (Art. 15(10)(1)(b)), Morocco (Art. 15(10)(2)), Bahrain (Art. 14(9)(1)(b)). Data exclusivity for product registered in another territory Panam, 15(10)(1)(b), Peru, Article 16(10)(1)(b), Colombia Article 16.10.1.

entities' and where the generation of data involves considerable effort[7]. The provision requires data protection with respect to any new product. The latter is loosely defined as 'one that does not contain a chemical entity that has previously been approved by the Party'. Such protection may be sought irrespective of whether any effort was spent in the generating the data (Mercurio, 2006).

It is worth noting that data exclusivity, under US PTAs, operates independently of the patent status: drugs that are unpatented, because no patent was obtained in the first place, can receive protection from generic competition for a minimum of five years (Shadlen, 2005).

Concerning pharmaceutical products, US PTAs link test data protection to the patent term, generic manufacturers may not obtain marketing approval at any time during the patent period, and even in preparation to enter the market upon patent expiry[8].

Several US PTAs[9] introduce provisions which prevent national drug regulatory authorities from registering a generic version of a drug that is under patent in the country without the consent of the patent holder. This provision represents a significant shift from traditional operating standards, where the market approval of a drug, that is the regulatory approval granted to a product which proves its safety and efficacy, has not been linked to a drug's patent status. Thus, the patent status of a drug has never had bearing on whether a drug is of sufficient quality, safety and efficacy to be marketed in a particular nation or region.

As a result, if a patent holder believes a generic manufacturer is infringing its patent, it traditionally has the responsibility to enforce its rights. In practice, this entails the patent holder bringing suit against the alleged infringer in an effort to prevent further sales of the infringing product and recover damages. This process can be lengthy and costly, but ensures the validity of a patent before enforcing the rights asserted by the plaintiff. In addition, IPRs have always been recognized as 'private rights' (TRIPS explicitly supports this position) and it seems logical that the owner of private rights should be responsible for their enforcement. The newly delegated role of the regulatory authority as an 'enforcer' of a private right is therefore a significant benefit to the rights holder.

[7] See Panama Art.15.10.4.a, Peru Art.16.10.4.a CAFTA-DR Art.15.10.1.c, Morocco Art.15.10.1, and Bahrain Art.14.9.1.c, Peru Art.16.10.1.c, Colombia Art.16.10.1.c, Oman Art.15.9.1.c and Panama Art.15.10.1.c.
[8] These rules are embodied in the PTAs with CAFTA-DR Art. 15.10.2, Colombia Art.15.10.4.a, Morocco Art. 15.10.4, Bahrain Arts. 14.9.4.a Oman 15.9.4.a.
[9] *See* Arts 19.5.3 of CAFTA-DR; 17.9.4 of US–Chile; 15.9.6 of US–Morocco; and 14.8.5 of US–Bahrain, Panama 15.10.4, Colombia 16.9.5, Peru 16.9.5, Oman 15.8.5.

In addition, this linkage plays as *de facto* patent, ensuring a minimum period of monopoly for pharmaceutical companies, preventing competition, and in some instances, it may even prohibit a generic manufacturer from seeking registration in a country. A period of data exclusivity could be detrimental to countries taking advantage of a compulsory license. The Data exclusivity and the linkage between market approval and patent statute could effectively render the compulsory license meaningless if it cannot make effective use of the license without repeating time-consuming and costly tests to obtain marketing approval of its drug (Mercurio, 2006).

3.3- Patent term extensions Patent revocation and right exhaustion

US PTAs extend patent protection term by engaging other parties to 'compensate' any 'unreasonable' delay in examining an application for registration, through extending the patent term in the same amount of time as the 'unreasonable' delay (often stated as a period extending beyond five years from the date of the filing or three years after a request for an extension)[10].

Moreover, US PTAs restricts the ability to revoke a patent to be " only on grounds that would have justified a refusal to grant the patent" [11]. Moreover, pre-grant patent oppositions were forbidden.[12]

Some PTAs[13], call Article 5.A.3 of Paris Convention as condition for the revocation, where forfeiture shouldn't be provided except in case where compulsory license would not compensate the claimed abuse. In addition, the article prevents any proceeding before two years from the granting of compulsory license. Thus, the space for refusal of patent is narrowed, and the function of compulsory license is counterbalanced to become a vehicle to protect patent holder right.

Some the US PTAs prohibit parallel importation[14]. However, a number of US PTAs with developing countries, including Chile, Jordan, and CAFTA-DR, are silent on the exhaustion of patent rights. However, the article linking market approval to patent status contains obligation stating that party couldn't export a patented product for reason other than

[10] For example, Article 15(9)(6) of the CAFTA-DR, Bahrain 14.8.6.a, Chile 17.9.6, Colombia Art.16.9.6.b, Panama Art.15.9.6.b, Peru 16.9.6.b, Jordan 23.a, Morocco, Oman Art.15.8.6.a Art.15.9.7.
[11] Morocco Art.15.9.5, Bahrain 14.8.4, Oman 15.8.4, Chile 17.9.4, CAFTA-DR Art.15.9.4, Peru Art.16.9.4, Panama Art.15.9.4, Colombia 16.9.4.
[12] In the case of US PTAs with Morocco, Oman, Bahrain
[13] with Panama, CAFTA-DR, Peru, Colombia
[14] US-Morocco (Article 15(9)(4))

for marketing approval requirements. Practically, this provision prohibit partner to be a source of parallel importation for their countries who are not member of PTAs with US.

3.4-Complsury licensing restrictions

The restrictions placed on compulsory licensing through PTAs exist at two levels. First, PTAs indirectly restrict compulsory licensing as a result of the data exclusivity provisions and the linking of market approval to patent status (Mercurio, 2006). Second, direct restrictions limit the grounds on which compulsory licenses can be issued. Unlike TRIPS, these provisions are drawn in the negative and confine the use of compulsory licences to specified cases, such as remedying an anti-competitive practice, public non-commercial contexts, national emergencies and other cases of extreme urgency, and the failure to meet working requirements[15].

4- EU's Patent Approach in PTAs

Patent provisions in EU PTA have changed over. The earlier versions commit parties to the implementation of TRIPS and to "the highest international standards of protection", with commitments to adhere to WIPO treaties (where EU is already member). As will be discussed below, those agreements contain TRIPS plus provisions. In addition, where those agreements do not contain dispute settlement mechanism, their inclusion in PTAs makes them enforceable.

However, in the first phase of EU agreements, due to TRIPS NT and MFN provisions, the EU was able to free-ride on the highest international standards set by the US in earlier PTAs with the same countries (Watal, 2014). According to TRIPS article 4, any PTA provision on IP matters that enters into force after the TRIPS Agreement and that consists of an "advantage, favour, privilege or immunity" shall be "immediately and unconditionally" accorded to the nationals of all other Members.

EU re-examined it strategy in PTA agreement concerning IP, which was manifested by launching the EU's *Strategy to enforce Intellectual Property Rights in third countries* of 2004, in which one of the suggested actions was to "revisit the approach to the IPR chapters of bilateral agreements, including the clarification and strengthening of the enforcement clauses". The EU apply this as part of its Global Europe Strategy, which provides that "[i]n negotiating PTAs, the IPR clauses should as far as possible offer identical levels of IPR

15 Such provisions appear in US PTA with Jordan Art. 4.20.

protection to that existing in the EU while taking into account the level of development of the countries concerned" (EC, 2011, p21).

The section proceeds as follow, firstly it analyses TRIPS plus engagement in WIPO treaties that parties have to accede or comply with in the EU (and US) agreements. Then it turns to analyze elements found in the second generation.

4.1- International agreements

All generation of European approach to IP include obligation or promotion to accede and apply agreements that was not included in TRIPS. Those agreements are the International Union for the Protection of New Varieties of Plants (UPOV) 1991, The Budapest Treaty on the International Recognition of the Deposit of Microorganisms, Patent Cooperation Treaty (PCT) and Patent Law Treaty (PLT). The impact of those treaties on the international law is the same as that of any other TRIPS-plus provisions; and for He (2010) in this way the "TRIPS Agreement is amended, even though the amendment is not applicable to all WTO Members".

There are three types of commitment: the accession to a treaty within a certain deadline, the endeavour to accede to a treaty and compliance with a treaty.

Before discussing TRIPS plus provisions of those treaties, it should be noted that most of studied EU PTAS have no reference to Doha declaration[16]. PTA with Andean community states that in interpreting and implementing the rights and obligations under the PTAs "the Parties shall ensure consistency with this Declaration".

4.1.1- UPOV 1991 [17]

The TRIPs Agreement leaves to each country's discretion whether to protect new plant varieties by means of patent or by effective *sui generis* system or by any combination thereof. Thus, developing countries are not obliged to provide for the protection of plant varieties under patents nor to comply with UPOV provisions, instead, they may prefer to develop their own *sui generis* system of protection.

The 1991 Act abandon the clear prohibition on double protection in 1978 Act (*sui generis* system and patent), so that a Contracting Party is, so far as the 1991 Act is concerned, free to protect varieties, in addition to the grant of a breeder's right, by the grant patents. (El-Saghir et al, 2006)

[16] PTAs with CARIFURM use a shallow language, that it "recognize the importance" of the Doha Declaration on the TRIPS"

[17] All EU studied PTAs include obligation to adhere to UPOV (1991).

UPOV '91 requires a comprehensive coverage of plant varieties by the member states. States that have been members of the Convention have a five year transition period to meet this requirement. New members to the Union, however, are required (Article 3) to protect 15 genera or species on accession (5 for UPOV 1978) and include all genera and species within 10 years (a minimum of 24 after 8 years).

Under the 1991 Act, the right of the breeder in respect of the production of propagating material is not limited to "production for the purpose of commercial marketing", rather it is extended to all production. Thus, breeder's authorization is needed in respect of the propagating material of a protected variety, any production or reproduction (multiplication), conditioning for the purpose of propagation, offering for sale, selling or other marketing, exporting, importing and stocking. As a general rule, farmer' would no longer be able to freely save and re-sow propagating material from the previous year's harvest where this is the common practice in developing countries. However, Article 15.2 provides an optional exception which permits Contracting States to restrict the breeder's rights, within reasonable limits and subject to the safeguarding of the legitimate interests of the breeder, in order to permit farmers to use for propagating purposes, on their holdings, the propagating material from the previous year's harvest[18]. however such exception is valid only for varieties which are essentially derived from the protected variety, where the protected variety is not itself an essentially derived variety (EDV), and for varieties which are not clearly distinguishable (El-SAGHIR et al, 2006).

Article 14(5), which provides for the inclusion of EDVs of protected varieties within plant breeders' rights, seeks to strengthen the rights of the breeder by bringing within protection "essentially derived and certain other varieties" of the protected varieties. Under this provision, the so-called "research exemption" available under UPOV 78, which allowed breeders to freely use protected varieties for research purposes and for breeding new varieties, was excluded (Dhar, 2002).

The duration of protection of breeders right under the 1991 Act for plant varieties was extended to not less than twenty years from the date of the grant of the breedesr's right (15 years in UPOV 1978), and for trees and vines the duration should not be less than twenty-five years[19].

[18] Article 15.2.
[19] Article 19.

4.1.2- The Budapest Treaty on the International Recognition of the Deposit of Microorganisms

This treaty was signed in 1977 as a means of facilitating compliance with the requirement of "disclosure" in the procedure for obtaining a patent. Normally, a written description of the invention is required to obtain a patent. Since such a description is difficult in cases where the invention involves a microorganism, the Budapest Treaty allows the deposit of microorganisms to be considered sufficient disclosure in these cases, and also provides international authorities with which this deposit may be made **(Vivas-Eugui, Oliva, 2010).**

As the term "microorganism" is interpreted broadly, encompassing any biological material whose deposit is necessary for purposes of disclosure – particularly in the food and pharmaceutical sectors – these rules can also be interpreted as tactics for facilitating and promoting patents on plants and animals. Although the Budapest Treaty do not affect patentability criteria, it complement and facilitate the description of the invention. Procedures for obtaining patents promote patent protection.

4.1.3- Patent cooperation treaty (PCT) and Patent Law Treaty (PLT)

The PCT provides patent owners with an easy and cost-effective mechanism to globally file patent applications. While individual nations still examine whether an application meets national criteria of patentability, a PCT application streamlines the process with an initial single application; National examination occurs later (Ho, 2011).

It provides the applicant with several benefits. First, the applicant can initiate a request for a patent in all countries that are members of the PCT; however, the high costs of many parallel national applications are deferred for a period of months and sometimes years. The lag time also enables an applicant to delay a decision concerning which countries are desirable for patent protection. Second, the applicant is entitled to a preliminary examination of its patent application through the PCT, which, if negative, may enable the applicant to elect not to pursue some or all national applications. While this may seem a small procedural detail, it may have significant implications, given that countries that are not members of the PCT are likely to have few patents filed (Ho, 2011).

Some countries have obligation to comply with or accede to Patent Law treaty established in 2001. The main objective of PLT is to harmonize the formal requirements relating to the procedures for applying for, obtaining and maintaining patents. The treaty contains a set of standardized formal requirements for national and regional patent offices to apply when dealing with patent applications. It covers: filing date, standardized forms,

procedures for examination, compliance with time limits, means for avoiding unintentional loss of rights and electronic filing (Musungu and Dutfiel, 2003).

The PLT, in effect, will enhance the position of patent owners by combining deregulatory measures with safeguards for them. For example, article 10 provides that non-compliance by a patent holder with one or more of the formal requirements under the treaty may not be a ground for revocation or invalidation of a patent except where fraudulent intention is proven. The burden of proof for fraudulent intention is usually very high (Musungu and Dutfiel, 2003). In addition it include obligation to give the patent applicant the opportunity to make observation, amendments and corrections, where such practice are "permitted under applicable law".

These tow treaties serve to eliminate indirect obstacles that could be used by national authorities in order to delay the deliverance of patent or to refuse it. After all, even if domestic laws offer the type of patent protection desired that protection is elusive if there are too many logistical hurdles to obtaining patent protection. The ability to use a PCT application removes such hurdles.

4.2- Expanding patentee exclusive rights

Thus, EU's latest proposal on IP in bilateral negotiations consists of detailed provisions on almost every issue covered by the (TRIPS). Actually, many of these provisions go beyond the minimum standards of TRIPS. The first translation to this shift was the EU-South Korea PTA in 2010 and the EU-Peru-Colombia trade agreement.

The definitions sometime go beyond those employed in the TRIPS Agreement, as they often include issues, which are still being discussed multilaterally (e.g. rights to traditional knowledge (TK), folklore and genetic resources) or have not been discussed at all (e.g. protection of non-original databases, utility model). EU PTA broadens the definition of intellectual property to include categories that wasn't considered IP in TRIPS. The agreement with CARIFURM and Andean community incorporate the protection of plant varieties in the definition of IP. In addition, it emphasis in the definition of IP that patent include biotechnological inventions.

Patent term extension is mandated in case of delays resulting from marketing approval procedure.

New PTAs[20] engages partner to grant an exclusivity period and the non-reliability, for data related to safety and efficacy, even if submitted in another party territory, of 10 years to (new) chemical agriculture product and 5 years for pharmaceutical products. Articl 231.3 of EU-Peru-Colombia defines the new chemical product as "the one which has not been previously approved in the territory of the Party for its use in a pharmaceutical or chemical agricultural product". Consequently, it forces parties to accord patent for new uses for known chemical entities.

4.3- Plants varieties

New versions of EU PTAs include provisions on patent varieties. In this respect, the EU-CARIFORUM PTAs, on the one hand, leaves the parties the freedom to provide for exceptions to the so-called plant breeders' rights[21], and on the other hand, by requiring the parties to accede to UPOV 1991 prevents them from exchanging or transferring the saved material to others. These two requirements are contradictory (Nadde-Phlix, 2014).

The EU-Col-Peru PTA is more straightforward regarding the protection of plant varieties (Article 232). The same applies to the PTA with Korea, which requires the parties to the agreement to provide for the protection of plant varieties and to comply with UPOV 1991.

4.4- Biodiversity, genetic resource traditional knowledge (CBD)

The protection of TK and biodiversity is a new component in the IP chapters of new EU PTAs, starting with the EU-CARIFORUM PTA. However, the related provisions reflect existing obligations under the CBD in addition to recognizing the importance of the CBD's objectives and principles.22 In this context, it is worth mentioning that the EU, Peru, Colombia, Central America, South Korea and the CARIFORUM States are members of the CBD and therefore are bound by its provisions. Many of these countries are also signatories of the Nagoya Protocol and hence will be bound by its provisions once the Protocol enters into force.

EU-CARIFORUM PTAs allows the parties to require "that the applicant identifies the sources of the biological material used by the applicant and described as part of the invention"[23] as a part of administrative requirements.

This provision is optional, as it authorizes but does not mandate national governments to apply it. Accordingly, the CARIFORUM States can make use of its provision; however,

[20] EU-Korea Article 10.36 and article 10.37, EU-Peru and Colombia Article 231.5
[21] It gives the parties "the right to provide for exceptions to exclusive rights granted to plant breeders to allow farmers to save, use and exchange protected farm-saved seed or propagating material"
[22] See Article 150 of the EU-CARIFORUM PTAs, Articles 196.4 and 201 of the EU-Colombia and Peru PTA, and Article 10.40 of the EU-South Korea PTA.
[23] Article 150.4

they cannot oblige the EU to apply it, and it does not mention the consequences of non-compliance. But the word "source", rather than "origin", gives it wider connotation and includes both geographical origins as the origin and/or supplier. This provision may be linked to the preamble to the European Biotechnology Directive, which provides for voluntary disclosure of the geographical origin of biological material (Vivas-Eugui, Oliva, 2010).

Provisions on GR and TK in EU-South Korea PTA, are similar to the ones provided in the EU-CARIFORUM PTA excluding any mention of the disclosure requirement issue[24].

The EU-Col-Peru PTA acknowledges "the usefulness of requiring the disclosure of the origin or source of genetic resources and associated traditional knowledge in patent applications"[25]. It also adds that "the Parties will provide, in accordance with their domestic law, for applicable effects of any such requirement so as to support compliance with the provisions regulating access to genetic resources and associated traditional knowledge, innovations and practices"[26].

Although one scholar interprets this provision as an obligation that would require the EU to amend its current Directive on Biotechnology in order to determine the effects of the lack of fulfillment (Vivas-Eugui, Oliva, 2010), another scholar suggests that Article 201 of the EU-Col-Peru PTA states principles of protection "subject to national legislation" that fail to create clear obligations of the EU to protect GR, TK and folklore (Drexl, 2014).

In sum it seems that the EU limits itself to IP concessions that reflect the level of protection available at the Community level (Nadde-Phlix, 2014). However, a safeguard clause has been included in most EU PTAs which enables parties to the Agreements to review the provisions relating to biodiversity and TK in the light of the results and conclusions of the related multilateral discussions[27].

5- China's Patent Approach in PTAs

The paper covers six Chinese trade agreements with ASEAN (2007), Pakistan (2009), Chile (2010), Peru (2010), Costa Rica (2011), and South Korea (2015). Those agreements either do not cover IPR or provide for very limited coverage. The first agreement with developing country to introduce a separate chapter on intellectual property is China-Peru agreement to be followed by agreements with both Costa Rica and South Korea.

[24] Article 10.40 of the EU-South Korea PTA.
[25] Article 201(7) of the EU-Col-Peru PTA.
[26] Article 201(8) of the EU-Col-Peru PTA.
[27] Article 150(6) of the EU-CARIFORUM PTAs, Article 201(13) of the EU-Colombia and Peru PTA and Article 10.40(3) of the EU-South Korea PTA.

Common element in those chapters is the emphasis on the need to attain a balance between patentee rights and the legitimate interest of users and community with regard to protected invention. In addition, they include engagement, though without practical implication, to prevent any practice that constitute an abuse of IPR by patentee and have the effect of adversely affecting or limiting technology transfer[28].

5.1- Genetic resource, traditional knowledge and folklore

In fact many developing countries have complained of bio-piracy, in which multinational firms take their traditional knowledge and genetic resources and use it to produce patented product that could be very profitable. Consequently, Developing countries had been pushing in various international forums to make mandatory the disclosure of the source and/or country of origin of biological resources, of associated, if such resources and traditional knowledge are contained in an invention over which an applicant is seeking patent rights. Those efforts produced the Convention on Biological Diversity (CBD), which is not signed by US yet.

Chapters on IPR in China's agreements include provisions on genetic resource, traditional knowledge and folklore. They affirm the principles and provisions established in the CBD, and encourage the effort to establish a mutually supportive relationship between the CBD and TRIPS Agreement. The agreement with Korea was signed after the conclusion of Nagoya protocol, so Article 15.17.2 affirms the "respect" to its requirement, "especially those on prior informed consent and fair and equitable sharing of benefits ".

Importantly, they affirm each country right to adopt or maintain any measure which aim to promote the equitable sharing of benefits arising from the use of genetic resources and traditional knowledge. Finally, they leave opened the possibility to negotiate in the future on the question of resource disclosure and prior informed consent obligations in patent applications.[29]

The textual language in the provision therefore clearly indicates that the protection of genetic resources, traditional knowledge and traditional cultural expressions is merely optional, not mandatory. Moreover, the protection the provision calls for is consistent with the intellectual property laws and policies of China. Article 26 of the Chinese Patent Law requires patent applicants to disclose the traditional knowledge and genetic resources used in their inventions (Zhuang, 2013).

[28] See Article 144 China-Peru trade agreement, Article 109 and 110 in China-Costa Rica trade agreement, Article 15.1 and Article 15.2China-South Korea trade agreement.
[29] Article 145 China-Peru trade agreement, Article 111 China-Costa Rica trade agreement, and Article15.17.4 China-Korea trade agreement.

5.2- Plant varieties

China-Korea trade agreement contains the most comprehensive chapter on IP and serves as example of extreme limit of provision on patent observed in studied agreement. In general, it restates commitments under TRIPS. Its definition of IPRs includes elements that were not contained in the TRIPS, at least separately e.g. plant verities and utility model[30]. In contrast, the definition does not mention elements that were covered in the TRIPS, e.g. Geographical Indication and Layout-Designs (Topographies) of Integrated Circuits (See Footnote 52).

Article 15.18 on plant varieties restates some commitments under the *International Convention for the Protection of New Varieties of Plants 1978* (UPOV 1978), where the two countries are already members. Article 15.18.3 stipulate: "The Parties shall respect regulations on new plant varieties protection of the other Party and grant adequate and effective protection to breeders of new plant varieties". And it establishes that the propagating material of the protected variety shall require the authorization of the breeder in case of: (a) production or reproduction (multiplication) for the purposes of commercial marketing; (b) conditioning for the purpose of commercial propagation; (c) offering for sale; (d) selling or other marketing; and importing or exporting.

Thus, farmers are free to save and re-sow propagating material from the previous year's harvest, as the permission of the breeder is only required for the production for "commercial marketing". Breeder's permission is not also required, either for utilization of the protected variety for the purpose of breeding additional new varieties or for the marketing of such varieties[31]. It should be noted that the Article 15.3 affirm also parties' commitments under UPOV 1978[32]. Given that Korea is a member of UPOV 1991, it seems that China does not accept engagement going beyond 1978. UPOV 1991 is criticized to favors breeders on framers, because it prevents all utilization of plant varieties by farmers without breeder consent. In fact, the accession to UPOV 1991 is recurrent obligation under US and EU trade agreement.

5.3- **Doha declaration**

[30] Article on utility models is too brief and contains no engagement. It simply states "party agree to enhance cooperation at this level".

[31] Article 5(3) of UPOV 1978.

[32] The two parties affirm their commitment in many treaties where they are already members, with no additional obligation to comply with or accede to other agreements.

Finally, a characteristic of Chinese patent provisions is the inclusion of a separate article on the Intellectual Property and Public Health that recognize principals established in Doha declaration[33].

This reference is of major importance, given that the existence of a number of flexibilities in the TRIPS Agreement has been confirmed by the WTO Ministerial Conference, the highest WTO body, through the Doha Declaration on the TRIPS Agreement and Public Health. The Declaration is the first WTO instrument to specifically use the concept of 'flexibility' with regard to the TRIPS Agreement (Correa, 2014).

Although the Doha Declaration focused on IPRs related to public health, it is relevant to IPRs in any field of technology. Paragraph 5 of the Doha Declaration[34] specifies some of the flexibilities available to facilitate access to pharmaceutical products. The wording of the chapeau of this paragraph makes it clear that it only enumerates some of the possible flexibilities. Sub-paragraph (a) confirms the relevance of article 7 of the TRIPS Agreement[35] for the interpretation of its provisions, thereby suggesting that the TRIPS Agreement must be interpreted in a manner that favors access by third parties to technology necessary to further innovation and domestic production. One important element of Doha declaration is the affirmation of members' liberty of to define the ground upon which they issue compulsory license. According to Correa (2014) Paragraph 5 is particularly relevant to the implementation of measures intended to expand domestic production with the use of protected technologies.

5- **Conclusions**

Empirical results show the systematics and clear tendency of North-South PTAs to eliminate, even to varied degrees, the TRIPS flexibilities. US's approach is the tightest where each aspect of TRIPS flexibilities is affected negatively restraining ability of its use. EU's approach seems evolved over time from basically introducing engagements to adhere

[33] China-South Korea Article 15.5, China-Peru Article 144.6, China-Costa Rica Article 112, China Chile Article 111.

[34] It states "while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

a. In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.

b. Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted"

[35] This article provides that the protection and enforcement of intellectual property rights 'should contribute to the promotion of technological innovation and to the transfer and dissemination of technology'. The Agreement should not be regarded as a charter of absolute rights to control the exploitation of protected technologies, but rather as an instrument that requires the use of such technologies 'to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare' (article 7).

and comply with WIPO treaties (an element that is included US approach), to converge to US approach in its PTAs. Consequently, *de jure* Policy Space for state practices aiming at the technological capabilities accumulation is substantially reduced in both US and EU's PTAs.

While India PTAs have no reference to any matter related to IP and patent, Chinese approach even pragmatic, where texts are varied from PTA to another. Patent related issues are either absent from Chinese trade agreements or covered limitedly. Its patent provisions are shallow, rhetoric and contain no additional commitments relative to parties' previous engagements. Consequently, they do not limit the ability of its partners to use TRIPS flexibilities in a framework of industrial policy aiming at fostering technological capabilities.

We can say that common elements in the India and China, are those which are not treated in their agreements, that's the absence of higher patent standards than those found in TRIPS. However it is apparent that the two countries do not promote any new model of patent regulation through their PTAs.

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